Remarks of Congressman Henry A. Waxman for
Biosimilars 2008
September 22, 2008

I appreciate having the opportunity to talk with you today.

As one of the authors of the 1984 Hatch-Waxman law, I am always pleased to have a chance to talk about generic drug issues. Simply put, generic drugs play an essential role in promoting the public health. Where they are available, they promote competition which in turn stimulates innovation. Competition also obviously lowers drug prices, and fosters access for many patients who might not otherwise be able to afford their medications. So we need to make sure that policies are in place that foster widespread access to generic drugs.

But, as you are all aware, for one of the most important and fastest growing type of drugs, a clear generic drug approval pathway simply does not exist—I'm referring of course to biotech drugs, or "biologics."

Many people believe that biotech drugs are the future of medicine, promising a new generation of life-saving medicines. They are also dramatically more expensive than traditional drugs. It is common for biotech drugs to cost tens of thousands of dollars a year per patient, even after patent expiration. Just coming up with the insurance co-pay on a $25,000/year drug can strain the budget of many Americans. For the 46 million uninsured Americans, that price tag can put a life-saving drug completely out of reach.

Biotech drugs are so expensive, they are also straining the budgets of big health-care payers like large employers and the federal government. In 2006, for example, the top 6 drug expenditures under Medicare Part B (drugs given in doctor's offices) were all for biotech drugs—that's over $4 billion spent on those 6 biologics.

Biotech drugs are also the fastest growing segment of the drug marketplace. In 2006, U.S. biotech sales grew by 20% to $40.3 billion. By way of comparison, this 20% growth in biotech sales is far greater than the 8% sales growth experienced by traditional pharmaceuticals.

This tremendous growth in biotech drugs' share of the market is in no small part due to the fact that, under current law, these drugs are entirely immune from generic competition.

That's because biologics were not clearly covered under the original Hatch-Waxman Act. So FDA currently lacks a clear pathway for approving low-cost competing versions of these drugs, even after patents have expired.

The absence of a generic pathway gives the makers of biotech drugs something like a super-patent. When there is no generic pathway, every competitor must repeat all the clinical trials, whether they are scientifically necessary or not. The cost of repeating the trials is so high that generic competition is not economically feasible. So the original manufacturer often enjoys a monopoly long after its patents expire.

Until and unless we in Congress act to give FDA authority to approve generic biologics, the biotech industry will continue to enjoy these permanent monopolies. And employers, insurers, and the federal government will continue to pay the staggering monopoly prices we have today.

I have always believed that fair competition is the best way to bring down drug prices. Generic competition has been very successful in reducing costs for traditional drugs, and it has not harmed innovation—it has actually spurred innovation. After all, when manufacturers have permanent monopolies, they don't need or want to innovate—new products would simply cut into their existing profits.

What principles should guide the development of a generic pathway?

- First, a good process must ensure safety and effectiveness. Biotech drugs are more diverse than traditional drugs and there will be no one-size-fits-all set of tests to ensure that generics are as safe and effective as the original product. FDA should be given the discretion to decide, on the basis of science, which biotech drugs can be safely copied and what studies need to be done to establish that the copy and original drug are clinically indistinguishable.

- Second, a good process must allow for improvements in scientific knowledge and technology. To ensure that Congress does not discourage scientific innovation, a good process must not inappropriately freeze 2008's scientific requirements into law.

- Third, a good process must not impose unnecessary procedural hurdles. Legislation must not establish rulemaking or guidance requirements whose primary effect is simply to delay generic competition.

- Fourth, a good process must ensure early resolution of patent disputes. Hatch-Waxman attempted to do this, but the procedures we used were frequently exploited to delay generic competition. We learned a lot from that experience. We must avoid the well-documented pitfalls in the Hatch-Waxman patent notification scheme.

- Finally, a good process must provide adequate incentives for innovation without unnecessarily delaying competition. Any intellectual property protections added onto existing patent protections must be adequately justified.

In the last couple of years, we have made remarkable progress toward the goal of creating such a pathway. We've come much farther towards the enactment of that pathway much sooner than I had expected.

Prior to 2006, legislation to permit approval of generic biologics simply did not exist. I am proud to have been one of the first Members of Congress to develop legislation to establish this pathway, and to do this along with Senators Clinton and Schumer, who introduced the bill in the Senate.

When I first introduced the bill, I expected that it would be the first step in a long process of debate and deliberation that would take years.

But I clearly underestimated the strength of the demand for affordable biotech drugs now. An impressive group of businesses, consumer groups, patient organizations, and purchasers—united in their frustration with the sky-rocketing monopoly prices and in their belief that something must be done now—has formed an effective coalition to push for the rapid passage of a generic biologics pathway.

Many members of Congress have joined me in recognizing that something must be done. There are now four different legislative proposals that have been circulated.

Even BIO has finally come around and abandoned its long-standing argument that generic biologics are scientifically impossible.

These are all promising signs. But we can't paint too rosy a picture. Some of these bills were developed—and got support—not because of the elements of competition they introduced, but the protections against competition they contained.

So we need to proceed cautiously here. We cannot accept just any piece of legislation that establishes a pathway for the approval of generic biologics. Many of the legislative proposals do not meet the principles I just laid out.

Some of them write into law scientific requirements that will be obsolete in a few years, if not already.

Some of them impose rulemaking and guidance requirements that are required for no other FDA-regulated products and that substantially delay generic competition.

Some of them do not ensure early resolution of patent disputes.

And some of them provide what appear to me to be unjustified and excessive intellectual property protections.

Let me focus on intellectual property. We need to make sure that there is a balance between, on the one hand, adequate incentives for innovation and, on the other, rapid market entry by generic products.

The biotech industry already received the right to patent term extensions back in 1984, under Hatch-Waxman. Patent term extensions were the principal incentive for innovation provided by Hatch-Waxman in exchange for generic competition.

So the biotech industry has had the benefit of extended intellectual property rights for all that time, but without being subject to generic competition. Now that they are finally facing the competition that traditional drugs have faced since 1984, the biotech industry is calling for 12,

14, and even 16 years of exclusivity. And most of the other legislative proposals that have been introduced would grant industry its wish there.

Keep in mind that Hatch-Waxman gives only 5 years of exclusivity to the most innovative drugs, and 3 years to less innovative products. The periods in some of the generic biologics legislative proposals are so long that they are not just unbalanced. They transform those legislative proposals into huge give-aways that replace adequate incentives with windfall profits. Brand companies should receive a reasonable term of exclusivity, but not one that is so long that it would rob consumers of the cost-savings appropriate generic competition brings.

As Hatch-Waxman should make clear, I am not opposed to appropriate periods of exclusivity to permit innovators to recoup their investments. Many have tried to argue that the fact that our generic biologics bill does not contain a period of exclusivity means that I believe there should not be any protection there. Nothing could be farther from the truth. Keep in mind that we introduced our bill very early on in this debate, at the end of the 109th Congress, when there were no other bills. At that point in time, people were debating about whether a pathway could be constructed at all. So we wanted to keep the focus on that issue. We knew that the debate would ultimately get to the topic of exclusivity—as it should—but we didn't want to distract from the question of the pathway at that early point.

So let me make this clear: those who point to our legislation as evidence that I am against having a reasonable term of exclusivity are wrong.

But I think it is critical that when Congress considers how long the term of exclusivity should be, we have the best information available to guide our decisions. As I have said repeatedly since the beginning of this debate, I believe that we must insist that the brand industry demonstrate—with specific data—what they need to continue to innovate and to explain why they need it.

Instead, to date, industry has only come forward with ever-increasing terms of exclusivity, accompanied by constantly changing arguments for why they need such exorbitant protection from competition.

Unfortunately, none of the arguments has been backed up with persuasive evidence.

Most recently, industry has produced a new study, by one of their long-time allies, showing that it typically takes between 12.9 and 16.2 years for biotech firms to "break-even" on their investment in the product. They argue that this study is the answer to the question of why a 14 year term of exclusivity is so critical to the continued vitality of the biotech industry.

But a study released last week by a leading economist from Boston University, Larry Kotlicoff, makes a very persuasive case that exclusivity periods this long will actually *decrease* innovation. Dr. Kotlicoff argues from well-established economic theory that "competition, not protection, is the true source of innovation." If we enact a bill with excessive monopoly protection we will harm medical advancement. True innovation comes from allowing new inventors to use existing discoveries as the building blocks for new inventions. Excessive

monopolies, on the other hand, especially when combined with evergreening opportunities, encourage only minor modifications in existing products by companies trying to extend their monopolies as long as possible. After all, no rational company with a monopoly-protected product would spend time and money developing true advancements that undercut their existing profits.

Dr. Kotlicoff points to the success of Hatch-Waxman in encouraging innovation. He also explains why there are no significant differences between drugs and biologics that would suggest the need for longer exclusivity.

Yet another recent industry argument for lengthy exclusivity is that the patents on biotech drugs are not as strong as the patents on traditional drugs. This argument certainly might be relevant, if true. But unsupported assertions are not evidence.

Today, there is certainly no shortage of patent litigation in the biotech industry. If the argument that biotech patents are more difficult to enforce is true, it should not be hard to provide evidence of a lower success rate in relevant patent infringement cases that are going on now.

Instead, we've seen just the opposite. One of the higher profile examples was Amgen's successful defense of its EPO patents against Roche last year.

This is only one case, of course. But before I accept the argument that biotech patents are weaker than traditional pharmaceutical patents, I'd like to see some real evidence that the EPO patents are the exception that proves the rule. I have repeatedly asked for this evidence and have never received anything but unsupported assertions.

Unnecessary exclusivity delays access to lower cost drugs and reduces innovation. Knowing that, we simply cannot rely on unsupported assertions.

The industry needs to provide some supporting facts -- something it has not done.

Over the last couple of years, we have made great progress toward the goal of creating a viable system for approving generic biologics. That is encouraging.

But I cannot emphasize too strongly that focusing on competition to address the cost to the consumer is critical. If that concern is not front and center, we will end up with a bill that only enhances the monopoly positions of the brands, and does more harm than good.

I am hopeful that we will see the establishment of the biogenerics approval system very soon.

We have every reason to be optimistic about the prospects for a thriving generic marketplace in the coming years. I am very hopeful that we will have a progressive Democratic administration next year. We can expect the next administration to have a significantly higher level of concern for the uninsured than our current President. Obviously, a key part of ensuring

affordable quality healthcare for the uninsured is a comprehensive drug benefit—cost is vital there, so we can surely expect an ever-increasing interest in getting generic versions of drugs on the market at the earliest possible moment.

I look forward to working with you in the coming years to get this done.